UNITED STATES DISTRICT COURT DISTRICT OF DELAWARE

MARY ANN MULLANEY, derivatively on behalf of BIOGEN INC,	Civil Action No.
Plaintiff,	
v. :	
GEORGE A. SCANGOS, PAUL J. CLANCY, STUART A. KINGSLEY, STELIOS PAPADOPOULOS, ALEXANDER J. DENNER, CAROLINE D. DORSA, NANCY L. LEAMING, RICHARD C. MULLIGAN, ROBERT W. PANGIA, BRIAN POSNER, ERIC K. ROWINSKY, LYNN SCHENK and STEPHEN A. SHERWIN,	JURY TRIAL DEMANDED
Defendants,	
and :	
BIOGEN INC.,	

Nominal Defendant. :

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

1. Plaintiff Mary Ann Mullaney ("Plaintiff"), by and through her undersigned attorneys, hereby submits this Verified Shareholder Derivative Complaint (the "Complaint") for the benefit of nominal defendant Biogen Inc. ("Biogen" or the "Company")¹ against certain current and/or former members of its Board of Directors (the "Board") and executive officers seeking to remedy the Individual Defendants' (defined herein) breaches of fiduciary duties, unjust enrichment, and violations of Section

¹ Until March 2015, the Company was known as "Biogen Idec Inc." or "Biogen Idec."

14(a) of the Securities Exchange Act of 1934.²

NATURE OF THE ACTION

- 2. According to its public filings, Biogen is a biopharmaceutical company that develops therapies for neurological, autoimmune and hematologic disorders. In 2006, Biogen acquired Fumapharm AG (a privately held pharmaceutical company formerly headquartered in Switzerland) and the rights to Tecfidera (also known as dimethyl fumarate), an oral (versus injectable) drug for the treatment of certain forms of multiple sclerosis ("MS"). Tecfidera, an immunosuppressant that is prescribed to treat multiple sclerosis ("MS"), was approved by the U.S. Food & Drug Administration ("FDA") in March 2013 and the European Commission ("EC") in February 2014.
- 3. Tecfidera was a core product and the main driver of the Company's revenues in 2014 and 2015, comprising between 32% and 34% of the Company's total revenue in Q4 2014, Q1 2015, and Q2 2015. In Q3 2014, Tecfidera revenue was approximately \$787 million, or more than 31% of total revenue.
- 4. Further, the defendants caused Biogen to emphasize the importance of Tecfidera in its October 22, 2014 Form 10-Q, stating that the Company's "current revenues depend upon continued sales of our principal products" including Tecfidera, and that Biogen "may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales of Tecfidera as we expand into

² While Plaintiff and her counsel have conducted their own, independent investigation, many of the facts and allegations contained herein, including the confidential witness ("CW") accounts and non-public internal documents, appear in the Class Action Complaint (the "Securities Complaint") filed against the Company and certain of its officers, which is related to many of the factual allegations contained herein. See Electrical Workers Pension Fund, Local 103, International Brotherhood of Electrical Workers v. Stuart "Tony" A. Kingsley, George A. Scangos, Paul C. Clancy, And Biogen Inc., No. 16-cv-12101-FDS (D. Mass., filed October 20, 2016) (the "Securities Action").

additional markets."

- 5. Beginning in the spring of 2014, the MS Institute at the Shepherd Center in Atlanta, Georgia, a leading prescriber of Tecfidera in the United States among MS centers, began conducting blood tests of MS patients taking Tecfidera to monitor for possible side effects. As a result of these tests, it has been alleged that the Shepherd Center started observing that there was an elevated risk of patients developing low lymphocyte counts among patients on Tecfidera. Lymphocytes are a subtype of white blood cells, and low lymphocyte counts compromise a patient's immune system. By way of comparison, some of these patients with lowered lymphocyte counts appeared to have laboratory values similar to that of a person suffering from Acquired Immune Deficiency Syndrome ("AIDS").
- 6. It has been alleged that by August 1, 2014, Dr. Ben Thrower ("Dr. Thrower"), the medical director of the MS Institute at the Shepherd Center, began notifying Biogen that Tecfidera was causing low lymphocyte counts among approximately 30% of the Shepherd Center's MS patients taking the drug. It has been alleged that Dr. Thrower expressed to Biogen the Shepherd Center's conclusion that Tecfidera was not as safe as the defendants were causing Biogen to publicly state. It has been alleged that this was expressed during in-person meetings in August and September 2014 with Keith Ferguson, Biogen's Senior Sales Director, as well as Eric Hall, Biogen's Medical Science Liaison. Dr. Thrower was no stranger to Biogen it has been alleged that from 2010 to 2013, he was one of the doctors involved in the ENDORSE clinical trial Biogen conducted for Tecfidera before the FDA approved the drug for sale in the United States.

- 7. It has been further alleged that an internal Biogen document confirms that during the second quarter of 2014 (*i.e.*, between April and June 2014), the defendants were aware that the Shepherd Center began removing patients from Tecfidera and the number of new starts and referrals (*i.e.*, new prescriptions of Tecfidera) "plummeted." It has been alleged that during the second and third quarter of 2014, the events at the Shepherd Center "began a domino effect in the territory which caused [other] neurologist[s] to also change their prescribing patterns away from Tecfidera."
- 8. It has been alleged that upon determining in approximately August 2014 that Tecfidera compromised patients' immune systems, the Shepherd Center completely stopped prescribing Tecfidera for MS patients. Further, it has been alleged that the Shepherd Center discontinued off Tecfidera at least half of the 400 patients who were taking that drug and transferred them to other therapies. It has been alleged that this was made known to the defendants by the Shepherd Center via the Shepherd Center's contacts at Biogen, including Biogen's: (i) Senior Sales Director; (ii) Medical Science Liaison; and (iii) Area Business Manager.
- 9. Defendants did not disclose any of these devastating developments to the public. Rather, they publicly trumpeted Tecfidera's safety profile and growing sales, and omitted any mention of the fact that the number one source of Tecfidera prescriptions in the United States, the Shepherd Center, completely stopped prescribing Tecfidera and discontinued off that drug at least half of its existing patients then taking Tecfidera because of its dangerous side effects.
- 10. On October 22, 2014, however, the defendants were forced to partially disclose the true safety profile of Tecfidera when they caused the Company to announce

that an MS patient who had taken Tecfidera for four and a half years as part of the ENDORSE clinical study died of progressive multifocal leukoencephalopathy ("PML"). PML is an infection caused by a virus that is dangerous for individuals with a weakened immune system. This was the first time that Tecfidera, which works by suppressing the immune system, had been publicly associated with PML. The PML death was caused by the exact same side effects—a weakened immune system—that it has been alleged that the defendants were made aware of months earlier during the second and third quarter of 2014 by the Shepherd Center, which at the time was the leading prescriber of Tecfidera among MS centers in the United States.

- 11. Critically, after the defendants announced the PML death on October 22, 2014, they repeatedly and misleadingly provided reassurances that the overall risk and safety profile of Tecfidera was unchanged, that doctors were continuing to prescribe it in increased numbers, that the number of patients as "new starts" on the drug continued to indicate sustained growth momentum, that doctors were not discontinuing patients off Tecfidera, and that Tecfidera would continue to drive strong revenue growth. On the same day they disclosed the PML death, the defendants provided assurances that "there is meaningful, still meaningful growth in Tecfidera in the United States, as we continue to penetrate doc[tor]s and penetrate the marketplace" and that they were "very comfortable with the trajectory of the product right now."
- 12. In touting Tecfidera's success, the defendants emphasized that "the way to think about Tecfidera growth is what portion of new starts" Tecfidera would capture (*i.e.*, new MS patients starting Tecfidera), patients switching over to Tecfidera from other drugs (referred to as "switches"), and market growth.

- 13. On November 25, 2014, a month after the defendants announced the PML death, the U.S. Food and Drug Administration (the "FDA") issued a warning and indicated that Biogen would update the Tecfidera label to include information regarding the PML death. The FDA recommended that physicians monitor patients on Tecfidera and "urge[d] health care professionals and patients to report side effects involving Tecfidera to the FDA MedWatch program."
- 14. Notwithstanding the label change, the defendants continued to express confidence in Tecfidera and its ability to drive revenue growth. On December 2, 2014, more than a month after announcing the PML death, the defendants claimed that the market for MS treatments was "moving to [oral medications] and the indicators that we have is [sic] that Tecfidera is unquestionably the leading oral [drug]." Defendants further stated that Tecfidera's discontinuation rates (*i.e.*, the rate at which patients were taken off the drug) are "very consistent" even though the Company hoped to "get better performance in the discontinuation rates over a longer period of time."
- 15. Similarly, in January 2015, the defendants caused Biogen to state that "that Tecfidera will continue to be a major business driver as it continues to expand in markets where it's already been introduced, and as we introduce it into additional markets around the world," and provided FY 2015 guidance of 14-16% revenue growth. Defendants further stated that the guidance was based on "Tecfidera ... represent[ing] the largest contributor to our overall revenue growth."
- 16. Defendants stated that they were working to educate doctors about the label change, and provided no indication that the PML death was materially impacting Tecfidera revenues beyond a minor effect on growth pace. In fact, defendants caused the

Company to state that "the lack of any meaningful change that we see...in the discon[tinuation] rate [of Tecfidera among patients] is encouraging, because it doesn't suggest that there's a change in the profile that people are anxious to pull patients out, but on the contrary."

- 17. During a February 25, 2015 analyst discussion, the defendants stated that they were "very comfortable with where Tecfidera is in terms of patient capture." Regarding the impact of the PML incident on physicians' perception of safety, they also stated that Tecfidera "has been quite resilient" in light of hesitancy by physicians to prescribe that would have otherwise been expected. On March 2, 2015, the defendants reiterated that Tecfidera was Biogen's "main driver here continuing to grow, continuing to do well for the Company's market share in MS treatment."
- 18. On an April 24, 2015 earnings call, the defendants partially (and belatedly) disclosed what they knew or should have known all along the PML death was having an impact on Tecfidera sales. However, the defendants misleadingly downplayed the impact of the PML incident on Tecfidera performance, stating that "our internal market research suggests that physician intent to prescribe may be improving. We believe these data indicate that we are assisting physicians in putting the updated label into context." Defendants did not update or correct the January guidance range for revenue growth, stating that Tecfidera continued to be "the largest contributor to overall revenue growth," with the long-term outlook for Tecfidera remaining "strong."
- 19. Defendants further stated that there was only "little unfavorable impact on the safety perceptions" from the PML incident, that it had already "stabilized," and that the Company was focused on turning it around. Asked how long the complete

turnaround would take, the defendants asserted that they had been educating physicians since November 2014, and that they "fundamentally believe that we...still have upward trajectory on Tecfidera from a share perspective, from a patient perspective, no doubt about it."

- 20. By May 2015, the defendants portrayed any fallout from the PML death as contained, stating that "physicians have kind of digested the information, taken it on board and their perspective about the safety profile of the drug has kind of gotten back to where it was before the PML event." According to the defendants, Biogen "continue[d] to see [its] share of capturing of new scripts and switched scripts higher than [its] share. That's usually an indication that we'll get upward momentum in the business."
- 21. Only two months after providing reassurances in late May 2015 that physicians' perception of Tecfidera's safety had "stabilized" back to where it was before the PML death, and three months after failing to correct guidance, the defendants disclosed the truth about the impact of the PML death on Tecfidera's performance. On July 24, 2015, before the market opened, the defendants caused Biogen to announce that the Company was cutting its revenue guidance in half, "based largely on revised expectations for the growth of Tecfidera."
- 22. In particular, the defendants caused Biogen to disclose that "[d]uring 2015, Tecfidera's U.S. patient growth versus prior quarters has moderated primarily due to changing physician prescribing patterns and intense competition." On an earnings call later the same day, defendant Scangos stated that the expected "reacceleration of Tecfidera this quarter... did not happen to any appreciable extent," and defendant Kingsley (defined further herein) acknowledged that "we saw moderated patient growth

for our MS portfolio as a whole this quarter.... We believe the safety event reported in late 2014 has created greater caution on the part of both physicians and patients about switching to orals." Defendant Clancy (defined further herein) also admitted that the "substantial decrease from our prior guidance" to "between 6% and 8%" revenue growth was "primarily driven by a change in our estimate for Tecfidera's trajectory. Our balance of year forecast assumes limited patient growth for Tecfidera in the United States."

- 23. On this news, Biogen's common stock plummeted from \$385.05 per share at the close on July 23, 2015 to \$300.03 per share at the close on July 24, 2015, a decline of more than 22% in a single day.
- 24. On July 27, 2015, a J.P. Morgan analyst report stated that "management credibility is clearly tarnished, and there's little doubt that the company is now stuck in the penalty box.... The messy 1Q report was supposed to be a one-time anomaly. Instead, 2Q results and revised guidance seem to indicate the problem is much more systemic. It's no wonder that investor confidence is shaken." Similarly, on July 27, 2015, a Morgan Stanley analyst report stated that "[Biogen management] has a credibility issue with its seeming inability to stem the now sig[nificant] decline in base business performance."
- 25. Shortly after disclosing the whole truth about Tecfidera, on October 9, 2015, the defendants caused Biogen to announce that defendant Kingsley, who was responsible for Global Commercial Operations, "will leave the company and a search has been initiated for a permanent replacement."
- 26. In light of the foregoing, Plaintiff issued a Demand (further defined herein) on the Board to investigate and take action against the Individual Defendants

named herein. The Board and a special committee of the Board (the "Special Committee") thereafter conducted an inadequate investigation and issued a wrongful refusal.

- 27. Specifically, and as discussed in more detail herein, the Board's and/or Special Committee's investigation was procedurally deficient because, *inter alia*: (1) the Board and/or Special Committee failed to create and/or provide a formal report detailing the substantive legal findings regarding the allegations raised in the Demand; (2) the Special Committee was represented by conflicted counsel; and (3) the Board and/or Special Committee failed to interview a single person who would not corroborate the defendants' claims of innocence (most notably, Dr. Thrower).
- As alleged herein, the Board's prejudgment and conclusory "analysis" of the merits of the claims set forth in the Demand, which was not aided by any independent counsel, is improper and demonstrates the Board's lack of diligence and good faith. In short, the entire "process" was procedurally deficient. The Board's abdication of its duty to properly investigate the Demand and to produce a formal report (or in the alternative, to provide Plaintiff with any formal report that was created or to even acknowledge that a formal report was created) was not reasonable, and was a decision made in bad faith, and is not entitled to the protections of the business judgment rule. Thus, Plaintiff has been left with no other recourse than filing this Action, and given the wrongful, bad-faith refusal of the Demand, this Action must be allowed to proceed.

JURISDICTION AND VENUE

29. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 in that this Complaint states a federal question. This Court has supplemental jurisdiction

over the state law claims asserted herein pursuant to 28 U.S.C. § 1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

30. Venue is proper in this District because Biogen is incorporated in this District. Further, Biogen engages in numerous activities and conducts business here, which had an effect in this District.

THE PARTIES

- 31. Plaintiff is a current shareholder of Biogen, and has continuously held Biogen stock since November 12, 2014.
- 32. Nominal defendant Biogen is a Delaware corporation, with its principal executive offices located at 225 Binney Street, Cambridge, MA 02142.
- 33. Defendant George A. Scangos ("Scangos") has served as the Company's Chief Executive Officer ("CEO") and as a director of the Company since 2010. In July 2016, it was announced that Scangos would leave the company.
- 34. Defendant Paul J. Clancy ("Clancy") has served as the Company's Executive Vice President ("EVP") and Chief Financial Officer ("CFO") since 2007.
- 35. Defendant Stuart A. Kingsley ("Kingsley") served as the Company's EVP Global Commercial Operations from November 2011 until October 2015.
- 36. Defendant Stelios Papadopoulos ("Papadopoulos") has served as a director of the Company since 2008 and as Chairman since June 2014. In addition, defendant Papadopoulos is a member of the Board's Audit Committee (the "Audit Committee"), the Board's Finance Committee (the "Finance Committee"), and the Board's Science and Technology Committee (the "Science and Technology Committee").

- 37. Defendant Alexander J. Denner ("Denner") has served as a director of the Company since 2009. In addition, defendant Denner serves as Chair of the Board's Corporate Governance Committee (the "Corporate Governance Committee") and is a member of the Finance Committee.
- 38. Defendant Caroline D. Dorsa ("Dorsa") has served as a director of the Company since 2010. In addition, defendant Dorsa serves as Chair of the Audit Committee and is a member of the Risk Committee.
- 39. Defendant Nancy L. Leaming ("Leaming") has served as a director of the Company since 2008. In addition, defendant Leaming serves as a member of the Audit Committee and the Risk Committee.
- 40. Defendant Richard C. Mulligan ("Mulligan") has served as a director of the Company since 2009. In addition, defendant Mulligan serves as Chair of the Science and Technology Committee and is a member of the Board's Compensation and Management Development Committee (the "Compensation Committee"). Finally, defendant Mulligan was a member of the Special Committee and was charged with investigating the Demand.
- 41. Defendant Robert W. Pangia ("Pangia") has served as a director of the Company since 1997. In addition, defendant Pangia serves as Chair of the Compensation Committee and is a member of the Finance Committee.
- 42. Defendant Brian Posner ("Posner") has served as a director of the Company since 2008. In addition, defendant Posner serves as Chair of the Finance Committee and is a member of the Corporate Governance Committee and the Audit Committee.

- 43. Defendant Eric K. Rowinsky ("Rowinsky") has served as a director of the Company since 2010. In addition, defendant Rowinsky is a member of the Compensation Committee, the Corporate Governance Committee, and the Science and Technology Committee.
- 44. Defendant Lynn Schenk ("Schenk") has served as a director of the Company since 1995. In addition, defendant Schenk serves as Chair of the Risk Committee and is a member of the Compensation Committee. Finally, defendant Schenk was a member of the Special Committee and was charged with investigating the Demand.
- 45. Defendant Stephen A. Sherwin ("Sherwin") has served as a director the Company since 2010. In addition, defendant Sherwin serves as a member of the Science and Technology Committee, the Finance Committee and the Risk Committee.
- 46. Collectively, defendants Scangos, Clancy, Kingsley, Papadopoulos, Denner, Dorsa, Leaming, Mulligan, Pangia, Posner, Rowinsky, Schenk, and Sherwin shall be referred to herein collectively as the "Individual Defendants" or the "Defendants."
- 47. Collectively, defendants Dorsa, Learning, Papadopoulos, and Posner shall be referred to as the "Audit Committee Defendants."

THE INDIVIDUAL DEFENDANTS' DUTIES

48. By reason of their positions as officers, directors, and/or fiduciaries of Biogen, and because of their ability to control the business and corporate affairs of Biogen, the Individual Defendants owed Biogen and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were and are required to use their utmost ability to control and manage Biogen in a fair, just, honest, and equitable manner.

The Individual Defendants were and are required to act in furtherance of the best interests of Biogen and its shareholders so as to benefit all shareholders equally, and not act in furtherance of their personal interests or benefits. Each director and officer of the Company owes to Biogen and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the business and financial affairs of the Company, and in the use and preservation of its property and assets, as well as the highest obligations of fair dealing.

- 49. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Biogen, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Biogen, each of the Individual Defendants had knowledge of material non-public information regarding the Company.
- 50. To discharge their duties, the officers and directors of Biogen were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Biogen were required to, among other things:
 - a. Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;
 - b. Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, as well as

- all contractual obligations, including acting only within the scope of their legal authority; and
- c. When put on notice of problems being experienced with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.
- 51. The Company's Code of Business Conduct ("Code of Conduct"), sets forth, in relevant part:

A conflict of interest occurs when you have a competing interest that may interfere with your ability to make an objective decision. Each of us is expected to use good judgment and avoid situations that can lead to even the appearance of a conflict. Conflicts of interest may be actual or just a matter of perception. Since these situations are not always clear-cut, you need to fully disclose them to your manager, Human Resources, Legal or Corporate Compliance so that we can properly manage them.

* * *

Our Company is subject to extensive and complex reporting requirements. Our operations must comply with all applicable regulatory, accounting, financial and other rules and regulations of the jurisdictions in which we operate. Business partners, government officials, investors and the public rely on the accuracy and completeness of our financial reports, business records and what we tell them. All of our financial records and accounts, and financial statements must be clear and complete, maintained in reasonable detail, and appropriately reflect our Company's transactions and activities. This includes our financial records and operational data such as cost and production data, expense reports and employee records. Accurate and complete information is also essential to us as a basis for sound decision-making. The Company's filings with the Securities and Exchange Commission, as well as other public disclosures by or on behalf of our Company, must be fair, complete, accurate, timely, and understandable. Our accounting and financial reporting practices must also comply with applicable generally accepted accounting principles and other criteria, such as local statutory reporting and tax requirements. Depending on their position with the Company, employees may be called upon to provide necessary information to assure that the Company's filings and public communications meet these standards. The Company expects

employees to take this responsibility seriously and to promptly provide current, accurate and complete answers to inquiries related to the Company's public disclosure requirements.

52. Pursuant to the terms of the Audit Committee's Charter (the "Audit Committee Charter"), the Audit Committee Defendants were and are specifically charged with overseeing, *inter alia*, the integrity of the Company's financial statements and the adequacy and effectiveness of the Company's system of internal financial and accounting controls.

SUBSTANTIVE ALLEGATIONS

A. Overview of the Company and its Core Product - Tecfidera

53. Biogen is a global biopharmaceutical company that develops and markets treatments for certain neurological, autoimmune, and hematological diseases. Tecfidera, one of four principal MS drugs the Company markets, is an oral therapy approved for use in the United States and the European Union to treat certain forms of MS. It was approved by the FDA in March 2013 and the EC in February 2014. Sales in the United States began in mid-2013. In 2015, the wholesale cost of Tecfidera per patient was approximately \$70,000. Thus, each lost sale represented a significant impact on Tecfidera revenue. From its launch, Tecfidera was a significant source of revenue for Biogen:

	Tecfidera	Total	Tecfidera Revenue as
	Revenue	Revenue	% of Total Revenue
Q2 2013 ^a	\$192,100,000	\$1,723,473,000	11.15%
Q3 2013 ^b	\$286,400,000	\$1,827,780,000	15.67%
Q4 2013 ^c	\$398,000,000	\$1,965,850,000	20.25%
Q1 2014 ^d	\$505,700,000	\$2,129,751,000	23.74%
Q2 2014 ^e	\$700,400,000	\$2,421,452,000	28.92%
Q3 2014 ^f	\$787,100,000	\$2,511,446,000	31.34%
Q4 2014 ^g	\$916,000,000	\$2,640,675,000	34.69%
Q1 2015 ^h	\$824,900,000	\$2,554,963,000	32.29%
Q2 2015 ¹	\$883,300,000	\$2,591,642,000	34.08%
Total	\$5,493,900,000	\$20,367,032,000	26.97%

^a Source: SEC Form 10-Q, dated July 25, 2013.

54. At relevant times, Tecfidera was Biogen's leading revenue source, accounting for more than 30% of total revenue:

	Tecfidera	Total	Tecfidera Revenue as
	Revenue	Revenue	% of Total Revenue
Q3 2014	\$787,100,000	\$2,511,446,000	31.34%
Q4 2014	\$916,000,000	\$2,640,675,000	34.69%
Q1 2015	\$824,900,000	\$2,554,963,000	32.29%
Q2 2015	\$883,300,000	\$2,591,642,000	34.08%

55. In Biogen's October 22, 2014 Form 10-Q for 2Q 2014, Defendants emphasized the importance of Tecfidera:

Our current revenues depend upon continued sales of our principal products, AVONEX, TECFIDERA, TYSABRI, and RITUXAN. We may

^b Source: SEC Form 10-Q, dated October 28, 2013.

^c Source: SEC Form 8-K, dated January 29, 2014.

^d Source: SEC Form 10-Q, dated April 23, 2014.

^e Source: SEC Form 10-Q, dated July 23, 2014.

f Source: SEC Form 10-Q, dated October 22, 2014.

^g Source: SEC Form 8-K, dated January 29. 2015.

^h Source: SEC Form 10-Q, dated April 24, 2015.

ⁱ Source: SEC Form 10-Q, dated July 24, 2015.

be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales of [Tecfidera] as we expand into additional markets.

56. During a January 12, 2015 JPMorgan Healthcare Conference, defendant Scangos stated that Tecfidera was a major business driver for the Company:

The products that we launched recently will continue to be major drivers and will play an increasingly large part in our pipeline obviously as we go forward. We believe that [Tecfidera] will continue to be a major business driver as it continues to expand in markets where it's already been introduced, and as we introduce it into additional markets around the world.

- 57. During the Company's January 29, 2015 earnings call, defendant Clancy emphasized that the Company's revenue guidance was chiefly dependent on Tecfidera: "Our plan assumes [Tecfidera] will represent the largest contributor to our overall revenue growth."
- 58. The Company's February 4, 2015 Form 10-K (the "2014 10-K") for the fiscal year ending December 31, 2014, which was signed by defendants Scangos, Clancy, Papadopoulos, Denner, Dorsa, Leaming, Mulligan, Pangia, Posner, Rowinsky, Schenk, and Sherwin, further stated that:

Product sales for AVONEX, TECFIDERA and TYSABRI and unconsolidated joint business revenues for RITUXAN each accounted for more than 10% of our total revenue for the years ended December 31, 2014 and 2013....

Our current revenues depend upon continued sales of our principal products, TECFIDERA, AVONEX, TYSABRI, and RITUXAN. We may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales and growth of [Tecfidera] as we continue to expand into additional markets.

59. During a March 2, 2015 Cowen Healthcare Conference, defendant Scangos referred to Tecfidera as "certainly our main driver" while discussing the

Company's growing market share in MS treatment.

60. The Company's April 24, 2015 Form 10-Q for 1Q 2015 stated:

Our current revenues depend upon continued sales of our principal products. We may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales of [Tecfidera] as we expand into additional markets.

61. Analysts also reiterated the importance of Tecfidera to Biogen. For example, in a January 30, 2015 research note after the Company announced 4Q 2014 earnings, Deutsche Bank noted that "FY14 results were driven by the strength of Tecfidera with 4Q revenues" and that Biogen's "[m]anagement continues to see Tecfidera growing in 2015." A Stock Report from S&P Capital IQ on May 4, 2015 wrote that S&P Capital IQ sees "revenue growth of 14.4% in 2015 ... following the 40.0% and 25.7% growth in 2014 and 2013, respectively, driven by ... Tecfidera."

B. Defendants First Become Aware of Serious Problems with <u>Tecfidera in 2014</u>

62. Dr. Thrower is the medical director of the MS Institute at Shepherd Center in Atlanta, Georgia. The Shepherd Center is a private, not-for-profit hospital. It has been alleged that from 2010 to 2013, Dr. Thrower was one of the doctors involved in the ENDORSE clinical trial Biogen conducted for Tecfidera. Dr. Thrower previously served as the medical director of the Holy Family Multiple Sclerosis Institute in Spokane, Washington. In Spokane, Dr. Thrower was the chair of the Inland Northwest Chapter of the National Multiple Sclerosis Society. In 2000, Dr. Thrower was awarded the Norm Cohn Hope Chest Award by the National MS Society, recognizing his work with the MS community. In 2005, Dr. Thrower was the first physician inductee into the Georgia Chapter of the National MS Society Volunteer Hall of Fame.

- 63. Dr. Thrower is a clinical instructor of neurology at Emory University and participates actively in clinical research. Dr. Thrower has served on the board of directors of the Georgia Chapter of the National MS Society and the board for the Consortium of Multiple Sclerosis Institutes. Dr. Thrower is currently a Senior Medical Advisor to the Multiple Sclerosis Foundation. In September 2015, Dr. Thrower co-authored a book titled, "Navigating Life with Multiple Sclerosis."
- 64. By August 1, 2014, the Shepherd Center in Atlanta was the leading prescriber of Tecfidera in the United States among MS centers. It has been alleged that as of August 1, 2014, approximately 400 of the Shepherd Center's MS patients were taking Tecfidera. It has been alleged that beginning in the spring of 2014, the Shepherd Center began conducting additional blood tests of multiple sclerosis patients taking Tecfidera to monitor for possible side effects. It has been alleged that as a result of those tests, the Shepherd Center observed that there was an elevated risk of developing low lymphocyte counts among patients on Tecfidera. Lymphocytes are a subtype of white blood cells. These lymphocyte counts in turn compromised those patients' immune systems. By way of comparison, some of these patients with these depressed levels of lymphocyte counts appeared to have laboratory values similar to that of a person suffering from AIDS.
- 65. It has been alleged that in approximately August 2014, Dr. Thrower began notifying Biogen that Tecfidera was causing this impact in approximately 30% of the Shepherd Center's MS patients who were taking Tecfidera. It has been alleged that Dr. Thrower expressed the Shepherd Center's conclusion that Tecfidera was not as safe as Biogen had been saying publicly. It has been alleged that Dr. Thrower also expressed the

Shepherd Center's concerns with Tecfidera during in-person meetings with Keith Ferguson, Biogen's Senior Sales Director, as well as Biogen's Medical Science Liaison Eric Hall, in August and September 2014.

- 66. It has been alleged that upon determining that Tecfidera compromised patients' immune systems, the Shepherd Center completely stopped prescribing Tecfidera for MS patients. Further, it has been alleged that the Shepherd Center discontinued at least half of the 400 patients taking Tecfidera—200 patients—taking them off the drug and transferring them to other therapies such as Teva Pharmaceutical's injectable drug called Copaxone. It has been alleged that the Shepherd Center's contacts at Biogen, including Keith Ferguson, Eric Hall, and Todd Burks, were aware of this development at the time because the Shepherd Center informed them that it was no longer prescribing Tecfidera for new patients and discontinuing existing patients.
- 67. It has been alleged that Confidential Witness 12 ("CW12")³ was an Area Business Manager at Biogen from March 2009 to July 2015 and worked in the Atlanta area. It has been alleged that an internal Biogen document provided by CW12--the 2014 Year-End Review for CW12 written in February 2015--confirms that Biogen was aware of the developments at the Shepherd Center. It has been alleged that in CW12's 2014 Year-End Review, Biogen Regional Director Craig Brown wrote that CW12's performance took a negative turn beginning in the second quarter of 2014 and through the third quarter of 2014 "due to a non-commercial event which impacted your number one

³ As discussed above, while Plaintiff and her counsel have conducted their own, independent investigation, the Securities Complaint from the related Securities Action contains numerous CW accounts and non-public internal documents. For ease of reference, all CWs are referred to herein by the same number as in the Securities Complaint.

MS volume and influencer account, ... Shepherd Center." It has been alleged that Brown wrote contemporaneously that:

The MS center medical director, Dr. Ben Thrower, and his partners began removing patients from Tecfidera, and the number of new starts and referrals subsequently plummeted. Dr. Thrower's actions began a domino effect in the territory which caused some of your community based neurologist[s] to also change their prescribing patterns away from Tecfidera.

- C. Defendants Cause the Company to Announce the First Death from PML, but Continue Issuing False and Misleading Statements Regarding Tecfidera
- 68. On October 22, 2014 (and cited to here for background purposes), Defendants caused Biogen to report its 3Q 2014 earnings of \$2.51 billion, including Tecfidera earnings of \$787.1 million. Defendants also caused the Company to report for the first time that an MS patient treated with Tecfidera had died of pneumonia after developing a rare brain infection from PML. Defendants caused the Company to state that it "reported the case to the regulatory authorities and will work with them to confirm that the language on [Tecfidera's] label provides patients and their physicians appropriate information...." However, Defendant Kingsley provided assurances that Defendants remained confident in Tecfidera:

[W]e are very comfortable with the trajectory of the product right now. We're very comfortable as we talked about the portion of new starts and switches we are getting.

Nothing significantly off plan from our standpoint. I think we feel pretty good about the performance.

69. Defendant Clancy stated that "there is meaningful, still meaningful growth in Tecfidera in the United States, as we continue to penetrate doc[tor]s and penetrate the marketplace." Asked if Defendants thought doctors would "reconsider use" of Tecfidera

in MS patients who could be at risk for developing PML, defendant Scangos responded only that they were "not in a position to make medical recommendations." Defendants did not indicate that they expected any negative reaction from physicians.

70. Analysts accepted Defendants' statements that the PML death would not have a material impact on Tecfidera. An October 22, 2014 Cowen and Company report stated:

Management disclosed for the first time a case of PML in a patient on Tecfidera who had a 3-year history of severe lymphopenia.... [T]he first report of PML in over 100,000 patients treated should not be concerning for the other 95% of the MS population.

71. Similarly, an October 22, 2014 Guggenheim Securities, LLC report stated:

Although additional PML cases would be a concern, we expect minimal impact from the single case on Tecfidera growth, given the event's rarity (1/~100K).... PML death should have little/no impact on Tecfidera adoption.... Importantly, however, we believe Tecfidera's PML risk will be perceived as low, given a single case in >100K patients dosed.

72. An October 22, 2014 report issued by RBC Capital Markets similarly stated:

[W]e think Tecfidera remains on a healthy trajectory in big picture [sic] and unlikely to be materially negatively impacted.... PML impact likely minimal....

- 73. On October 22, 2014, a Wells Fargo Securities, LLC analyst stated:
- BOTTOM LINE: We see minimal commercial impact and believe shares are overreacting to the PML report.
- 74. On November 25, 2014, the FDA issued a warning to the public regarding the patient who died from PML while using Tecfidera. The FDA stated that the patient was not taking any other drugs associated with PML, and advised physicians and patients to monitor for side effects. The FDA further noted that "[a]s a result, information

describing this case of PML ... is being added to the Tecfidera label."

75. On December 2, 2014, more than a month after announcing the PML death, Defendants claimed that the market for MS treatments was "moving to [oral medications] and the indicators we have is [sic] that Tecfidera is unquestionably the leading oral [drug]." Defendants further stated that Tecfidera's discontinuation rates (i.e., the rate at which patients were taken off the drug) were "very consistent" even though the Company hoped to "get better performance in the discontinuation rates over a longer period of time."

D. Notwithstanding Defendants' Reassurances, the Problems with <u>Tecfidera Drastically Impact the Company's Financial Results</u>

- 76. The low lymphocyte counts that the Shepherd Center observed as a result of the tests it began conducting in the spring of 2014, and that Shepherd Center communicated to Biogen before the PML death was announced, are the same underlying condition that led to the PML patient death that Biogen announced on October 22, 2014. The PML death confirmed for the Shepherd Center its conclusions regarding Tecfidera's safety profile. It has been alleged that as a result of the blood tests the Shepherd Center conducted and Biogen's announcement on October 22, 2014, physicians at the Shepherd Center (including Dr. Thrower) and health care professionals (nurse practitioners and physician assistants) at the Shepherd Center immediately lost confidence in the safety profile of Tecfidera.
- 77. It has been alleged that CW12 confirmed that Biogen was aware of the immediate and drastic impact the PML death had on Tecfidera sales and that it also resulted in many discontinuations. It has been alleged that most of the doctors CW12 sold Tecfidera to discontinued patients off the drug because of the PML death.

- 78. It has been alleged that in CW12's 2014 Year-End Review written in February 2015, Regional Director Craig Brown wrote that CW12's performance in 2014 took a negative turn "due to a non-commercial event which impacted your number one MS volume and influencer account, ... Shepherd Center."
- 79. It has been alleged that Brown then wrote that "your Atlanta South territory is one of [the] few in the nation that has a BIIB [Biogen] share above 50%," which leads to the reasonable inference that the rest of the nation was doing even worse than CW12's territory.
- 80. It has been alleged that Confidential Witness 11 ("CW11") was a Senior Territory Business Manager at Biogen from September 2012 to January 2016. It has been alleged that CW11's territory was in Pennsylvania and his largest client was the University of Pennsylvania's Medical Center (referenced hereafter as "Penn" or "UPenn"). It has been alleged that CW11 confirms that the October 2014 PML announcement had a substantial impact on both physicians' and patients' safety perception of Tecfidera which, in turn, directly impacted sales. It has been alleged that CW11 provided several internal Biogen documents that corroborate this information and provide specific details regarding the impact of the PML patient death on Tecfidera sales and physician confidence.
- 81. Tecfidera sales were very strong before the PML death was announced. It has been alleged that CW11's mid-end review for 2014 stated that in "Q1 [of 2014] Tecfidera showed the most success at 120% of plan. Again physicians saw the efficacy, safety and desire from patients to be on an oral 2X daily treatment." The second quarter of 2014 was strong as well, with Tecfidera sales at 103.2% of plan.

82. It has been alleged that CW11's sales of Tecfidera dropped precipitously immediately after the announcement that a patient had died while on Tecfidera, as it has been alleged that an internal Biogen document confirmed this. It has been alleged that CW11's 2015 mid-year review noted:

2014 was a very strong year in Q1, Q2, & Q3 for the entire portfolio. Following the PML Q4 experienced immediate impact and it is as follow[s]:

2014

Q4 TEC[FIDERA sales were] 78% [of plan] 74[sales]/94[target]

2015

Q1 TEC[FIDERA sales were] 36.7% [of plan] 29[sales]/79[target]

Q2 TEC[FIDERA sales were] 35.1% [of plan] 20[sales]/57[target]

83. It has been alleged that CW11's year-end review in 2015 confirms that the third quarter of 2015 was also negatively impacted:

Q3 [2015] again was impacted with the additional news of PML. I am concerned about the impact from Penn as I previously mentioned they do not have a solid strategy in place to monitor lymphocytes in their patients so Tecfidera is no longer in their minds an easy to start drug.

- 84. These figures confirm and bolster the information regarding drastically declining sales of Tecfidera that other Biogen employees throughout the United States confirmed during the same time period.
- 85. It has been alleged that CW11's mid-year review for 2015 provides how the patient death immediately and drastically impacted physician confidence in Tecfidera by the first quarter of 2015, completely contrary to what Biogen was publicly stating:

[Biogen's reduction in sales goals] demonstrated . . . how the Philadelphia market was impacted. Unfortunately, Q1 could not be saved... Penn was the first account to proactively stop rxing [prescribing] Tecfidera upon the

safety announcement. Penn represents about 60% of the Philadelphia West territory. The impact was far beyond what we could have anticipated. Dr. Jacobs had a lot of concerns about the safety of Tecfidera due to the fact that she was a PI for the trials of Tecfidera. In addition many others expressed the same concern. Q2 appears to [be] a bit more promising with Penn but the uptake has been stagnant. Gilenya⁴ seemed to gain momentum as the oral of choice due to the safety with Tec.

86. Defendants knew (or should have known) that Tecfidera sales would plummet immediately after the PML death was announced, contrary to what Defendants were causing the Company to state, because Defendants caused the Company to quickly and drastically lower sales targets for the drug. It has been alleged that CW11's mid-year review for 2015 quotes an internal Biogen email sent to employees in early 2015 stating that the Company was cutting sales goals for Tecfidera across all regions and territories for the second quarter of 2015:

The residual impact of the safety event from 2014 along with competitive pressure has continued to impact Tecfidera performance in Q2, but several leading indicators of success are encouraging, such as physician intent to prescribe, and an improving efficacy perception. To support your focus on executional excellence and establishing Tecfidera as the first choice, Tecfidera goals will be reduced by 15% across all territories and regions for Q2.⁵

- 87. Based on internal Biogen documents, it has been alleged that Biogen tracked CW11's sales targets and performance on a quarterly basis. The 15% reduction in Q2 2015 was just a beginning, because his sales goals were lowered even more that quarter by a whopping 28%. And his sales goals had already been lowered for Q1 2015 by 16% from the previous quarter.
 - 88. During this same time period, it has been alleged that internal Biogen

⁴ Gilenya is a drug used to treat MS sold by Novartis AG ("Novartis").

⁵ It has been alleged that CW11 also confirmed that Biogen announced no other adjustments to sales goals for other drugs during his tenure.

documents confirm CW11's sales goals for a different MS drug, Tysabri, remained steady, demonstrating that the decline in sales goals was limited to Tecfidera.

89. It has been alleged that CW11 also provided a PowerPoint slide deck titled Biogen "2015 Q2 Quarterly Business Review – Philadelphia West" that confirms not only the immediate and material impact of the PML death on Tecfidera sales and discontinuations, but that Biogen was aware of it. The Quarterly Business Review states that safety was a major concern at Penn and indicates that patients were being discontinued off Tecfidera:

In the oral market Tecfidera is down and Gilenya is up. Major factors: SAFETY is a major concern at Penn. PML and low lymphocyte counts (in the upwards of 4 months after being DC'd [i.e., discontinued] seem to have the most impact on their use of Tecfidera. In addition they have seen breakthrough with Tecfidera patients and believe Gilenya is more efficacious. Copaxone is considered their safest alternative.

90. The reference to a "breakthrough" is explained later in the Quarterly Business Review, where it is clarified to explain that among patients taking Tecfidera, diseases were breaking through "with tec[fidera]." The same slide also explains the challenges Biogen faced:

Challenges: UPENN – They believe there is a direct correlation between JCV⁶ status and PML with Tec. Patients may not be started on Tec if they are positive. Also have concerns with the lymphocyte counts in tec patients, when they go below 500 they are not going up to normal for outwards of 4 months. They have also sited [sic] breakthrough disease with tec, more than they have been with Gilenya.

91. The Quarterly Business Review concludes with a slide titled "2015 Territory Critical Success Factors" that demonstrates Defendants were aware that the PML death was having a drastic impact on Tecfidera:

⁶ JCV is a virus associated with PML.

- Turn Tecfidera around ASAP
- Major focus on UPENN to get them back to being confident in the safety and efficacy because their attitudes and philosophies are transferring to the community
- They are 60% of our direct business and influence 60% of our territory.
- 92. It has been alleged that CW1 was a Biogen Area Business Manager ("ABM")⁷ from November 2010 to June 2015, and was responsible for parts of southern Florida and Puerto Rico. It has been alleged that CW1 reported to Regional Director Robert Nelson, who reported to Senior Sales Director Keith Ferguson, who reported to Vice President Todd Nichols, who reported to Vice President of U.S. Commercial Joe Ciaffoni, who reported to defendant Scangos. It has been alleged that according to CW1, Tecfidera sales in his region dropped steeply and immediately after the public announcement of the PML death, and there was a large drop in new prescription sales of Tecfidera beginning around November 2014 by almost all of the neurologist customers in his sales territory. It has been alleged that CW1 stated that on a regional conference call chaired by Regional Director Nelson ("Nelson") in late 2014 following the PML incident, Nelson told ABMs that their region was not the only region where Tecfidera sales were poor; according to Nelson sales were down in almost every region across the United States.
- 93. It has been alleged that CW2 was a Market Research Manager for Biogen from 2005 to December 2014, reporting to Antonio Melo, the Senior Manager of

⁷ According to Biogen (*i.e.*, Defendants), an ABM is a "specialty sales representative position [that is] called upon to sell our Neurology products with key stakeholders in the Multiple Sclerosis community: including Neurologists, allied health professionals, and local MS chapters."

Business Planning. It has been alleged that CW2 attended a Company Town Hall meeting in November 2014 led by defendant Scangos. It has been alleged that according to CW2, Scangos' presentation (which took place the month after the PML death was announced and included a visual component that reflected his talking points) stated that "the overall sense of the trajectory [at Biogen] was changing." The Town Hall meeting also included a presentation on potential organizational changes as a result of the PML death. It has been alleged that it was CW2's understanding that the organizational changes stemmed from, among other issues, executive management's expectation that the PML death would have "an impact on performance."

94. It has been alleged that CW3 was a Biogen ABM responsible for certain parts of southern Florida and Puerto Rico from May 2012 to June 2015, reporting to Robert Nelson and then Manuel Dueno, who reported to Senior Sales Director Keith Ferguson, who reported to Todd Nichols, who reported to Senior Vice President of U.S. Commercial, Joe Ciaffoni. It has been alleged that CW3's responsibilities included selling Tecfidera to neurologists. It has been alleged that CW3 stated that his Tecfidera sales were strong until late 2014/early 2015, when sales dropped dramatically and failed to recover by the time he left Biogen in June 2015. It has been alleged that CW3 confirmed that there was a large drop in new prescription sales of Tecfidera beginning around November 2014 by almost all of the neurologist customers in his territory. It has been alleged that based on conversations with his neurologist customers, CW3 attributed the decline in sales to the PML death and the subsequent FDA label change in November 2014. It has been alleged that according to CW3, ABMs in other Biogen regions reported that their Tecfidera sales also had decreased dramatically by at least January 2015.

- 95. It has been alleged that CW3 attended a national sales meeting in Texas around March 2015, where the PML incident was described as a "market event" and that Tecfidera sales were not on track. It has been alleged that according to CW3, speakers at the meeting stated that sales would need to pick up again if the Company was going to meet expected 14-16% revenue growth.
- 96. It has been alleged that CW1 also recalled a national sales meeting in Texas in March 2015. It has been alleged according to CW1, senior Biogen leaders at the meeting acknowledged that the PML death definitely was impacting Tecfidera sales. It has been alleged that CW1 stated that at a Tecfidera "town hall" meeting led by Ciaffoni, Ferguson, and Nichols, metrics and graphs were presented that showed a sharp decline in Tecfidera sales in most regions. It has been alleged that according to CW1, one presenter stated that "we understand that the market event [i.e., the PML incident] has had an impact on [Tecfidera] sales."
- 97. It has been alleged that CW4 was a Biogen ABM from March 2006 to June 2015 and was responsible for parts of Kansas and northern Oklahoma. It has been alleged that CW4's duties included selling MS products, including Tecfidera, to neurologists. It has been alleged that CW4 reported to Regional Director for the Midwest region Renee Mercer, who reported to National Sales Director Bill West. CW4 stated that his Tecfidera sales dropped appreciably very early in 2015, while sales of other MS drugs continued to do very well. It has been alleged that according to CW4, new prescription rates dropped, and physicians were transferring patients off Tecfidera and onto different therapies. It has been alleged that CW4 received quarterly sales goals from Biogen's corporate office and stated that he did not meet his Tecfidera sales goals in 2015. It has

been alleged that in 2015, CW4 participated in biweekly conference calls with other regional ABMs and Renee Mercer, where Midwest region ABMs reported that they were not meeting their Tecfidera sales goals, up until the time of CW4's departure in June 2015.

- 98. It has been alleged that CW5 was a Biogen ABM responsible for neurology sales, including MS drugs, in areas of North Carolina and Virginia (in the South Region) from April 2013 to April 2015. It has been alleged that CW5 reported to Jason Romano, the Associate Director of Divisional Operations Patient Services, who reported to Keith Ferguson, the Senior Sales Directors, who reported to Todd Nichols. It has been alleged that CW5 stated that Tecfidera was his "lead product" by early 2014, but recalled a "big slowdown" in Tecfidera market expansion beginning in late October/November 2014 that he discussed with other Biogen neurology ABMs. It has been alleged that according to CW5, there was a linkage between the PML death and the drop in Tecfidera sales.
- 99. It has been alleged that CW5 stated that other ABMs in the South Region discussed on conference calls how poorly their Tecfidera sales were doing throughout the first quarter of 2015. It has been alleged that CW5 also began to experience a serious downturn in "start forms" for Tecfidera at the end of 1Q 2015, from 10 to 14 per week to 3 per week around March 2015.
- 100. It has been alleged that CW6 was a Biogen ABM in the Company's Western Region, responsible for sales in Montana, Idaho and Wyoming from 2011 through August 2015. It has been alleged that CW6 reported to Regional Sales Manager Chris Stoll, who reported to Senior Sales Director Bill Ames. It has been alleged that

CW6 stated that prior to the October 2014 announcement of the PML death, Tecfidera had a "hockey stick" (*i.e.*, exponential) growth. It has been alleged that following the October 2014 announcement, CW6 stated that his Tecfidera new starts declined by the end of 2014, and that after October 2014, new prescriptions significantly slowed down. It has been alleged that according to CW6, there was a "significant slowdown of people being put on" Tecfidera and people were more cautious following the PML death. It has been alleged that CW6 learned during conference calls that the decline or stoppage in new Tecfidera patients following the PML death occurred in other regions following the October 2014 announcement. It has been alleged that CW6 stated that Tecfidera sales never rebounded in 2015 before his departure in August 2015, and there was a significant slowdown during that time.

- 101. It has been alleged that CW7 was a Biogen ABM in the Company's Virginia region from April 2011 to June 2015, responsible for sales of Tecfidera to neurologists in parts of Virginia, West Virginia, and Maryland. It has been alleged that CW7 reported to Regional Sales Director Jason Lavinder, who reported to Senior Sales Director-East Stephen Hulse. It has been alleged that CW7 stated that his Tecfidera sales were consistently good prior to the announcement of the PML death in October 2014, but that after the PML announcement his territory "took a hit" beginning in December 2014 or January 2015.
- 102. It has been alleged that CW8 was the Senior Director of Commercial Operations for Biogen from August 2014 to November 2015, a position equivalent to Chief of Staff for the Head of Commercial Operations. It has been alleged that CW8 initially reported to Todd Nichols and later to Joe Ciaffoni, the Senior Vice President of

US Commercial. It has been alleged that CW8's responsibilities included oversight of operations related to Biogen's MS and hemophilia drugs, including Tecfidera. It has been alleged that during his tenure at Biogen, CW8 handled operational issues related to Tecfidera on a daily basis. It has been alleged that CW8 stated that all of 2015 was "difficult" for Tecfidera and that beginning with the "event in October," he could not recall a time when Tecfidera's sales prospects were not a concern.

- 103. It has been alleged that CW9 was a Biogen ABM responsible for parts of Connecticut and New York from July 2009 to March 2015, reporting to Regional Director Karen Grant, who reported to National Sales Director Stephen Hulse, who reported to Vice President Todd Nichols, who reported to Senior Vice President of U.S. Commercial Joe Ciaffoni. It has been alleged that CW9's responsibilities included selling Tecfidera to neurology practices and an MS center. It has been alleged that CW9 observed that the ABMs in his territory were not compensated for their Tecfidera sales in 1Q 2015, *i.e.*, they did not meet their Tecfidera sales for that quarter.
- 104. It has been alleged that CW10 was an Executive Assistant from July 2012 to October 2015 in Biogen's Program Leadership & Management team, supporting numerous programs including Tecfidera. It has been alleged that CW10's responsibilities included supporting the Program Executive and Program Director of Tecfidera; initially Alpna Seth ("Seth"), who then was replaced by Uthra Sundaram ("Sundaram") prior to the October 2014 PML announcement. Sundaram was a "dotted line" report to Scangos.
- 105. It has been alleged that according to CW10, Sundaram met weekly with Kingsley and Scangos, and quarterly with Clancy. It has been alleged that CW10 stated that after the PML death, Biogen's sales and commercial teams monitored sales numbers

through various reports. It has been alleged that according to CW10, Biogen immediately reached out to the top prescribing doctors as well as big pharmaceutical companies such as CVS Caremark and Walgreens after the PML announcement. It has been alleged that CW10 stated that Biogen's commercial team performed "deep drill downs" into sales numbers, including reviews of specific territories that were lagging, and that Sundaram went on "ride-alongs" with Biogen's Medical Science Liaisons, where Sundaram would meet with doctors to discuss the PML death.

- 106. It has been alleged that according to CW10, the entire Tecfidera team would meet during weekly program team meetings to discuss Tecfidera sales numbers and how the PML death affected sales. It has been alleged that CW10 stated that Sundaram communicated with Scangos and other senior executives following those meetings. It has been alleged that CW10 further stated that Sundaram was involved in the Tecfidera label change after the PML death and knew that the label change would immediately lead to lost sales.
- 107. It has been alleged that CW1 had access to his region's sales information, including the number of prescriptions written. It has been alleged that according to CW1, Regional Director Nelson would access other regions' sales metrics to compare their region's performance with that of other regions in the United States.
- 108. It has been alleged that CW4 also confirmed that the Company tracked sales metrics and prescriptions. It has been alleged that CW4 stated that when a prescription was sold, Biogen's headquarters knew about it.
- 109. It has been alleged that CW7 also stated that corporate headquarters would have had up to date insight into new prescription rates. It has been alleged that CW7

stated that forms needed to be filled out for every new Tecfidera prescription and that corporate offices were given copies of these forms. It has been alleged that according to CW7, his territory's sales reports were updated nightly and included the ID number assigned to every new patient and the name of the prescribing neurologist. It has been alleged that CW7 stated that the number of new prescriptions dropped after the PML announcement.

- 110. It has been alleged that according to CW1, sales goals for Tecfidera were adjusted downward in December 2014 to make it easier for ABMs to make compensation goals. It has been alleged that CW1 stated that many ABMs in his region still failed to meet the lowered goals.
- 111. It has been alleged that CW5 confirmed that the Company lowered Tecfidera sales goals around the same time. It has been alleged that according to CW5, in January 2015, Todd Nichols, Biogen's Vice President sent an email to ABMs that announced compensation thresholds for sales representatives were being lowered because of "lower guidance due to unforeseen market events" that it has been alleged that CW5 understood were based on problems with Tecfidera sales.
 - E. The Individual Defendants Continue to Make and/or Cause the Company to Make Numerous False and Misleading Statements Concerning Tecfidera
- 112. Following the announcement of the PML death and the FDA's advisory, and contrary to the material decrease in sales reported internally by sales personnel across all regions, Defendants publicly dismissed concerns that the PML death would materially impact Tecfidera performance. Defendants provided reassurances that Tecfidera would continue to drive double-digit revenues for Biogen in 2015.

113. On December 2, 2014, defendant Clancy attended a Deutsche Bank conference. Defendant Clancy made the following false and misleading statements at this conference:

Robyn Karnauskas - Deutsche Bank - Analyst

Tecfidera is capturing around a third of new patients and 40% of the switch market.

Do you think at this point Tecfidera is settling nicely at 35% market share in the overall market? Or where do you see Tecfidera going?

Defendant Clancy

[W]e still feel the market, broadly speaking, is moving to orals and the indicators that we have is that Tecfidera is unquestionably the leading oral... we think there's plenty of tailwind still left.

- Tecfidera is unquestionably the leading oral" and that Clancy believed there was "plenty of tailwind still left" were false and misleading because he knew (or should have known) there had been a "big slowdown" in Tecfidera market expansion by November 2014 and that sales were down in almost every region in the United States. Further, this statement was false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug.
- 115. On January 12, 2015, defendant Scangos attended a JPMorgan conference.

 Defendant Scangos made the following false and misleading statements regarding

 Tecfidera's ability to drive business:

2014 was a really good year for Biogen ... and we believe that this can be sustained going into the future. Our core business based on our existing suite of products is robust. Products continue to do well.

* * *

We believe that [Tecfidera] will continue to be a major business driver as it continues to expand in markets where it's already been introduced, and as we introduce it into additional markets around the world.

116. Defendant Scangos' statements that: (1) Biogen's performance in 2014 "can be sustained going into the future"; (2) the Company's "core business based on our existing suite of products is robust"; and (3) "Tecfidera will continue to be a major business driver" were false and misleading because of the immediate and significant impact the PML death had on Tecfidera sales in late 2014 and into 2015. These statements were also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug. In addition, these statements that Tecfidera's core business was "robust" and that Tecfidera would "continue to be a major business driver" were false and misleading for the additional reason that, at a minimum for the second quarter of 2015, Defendants caused Biogen to lower sales goals across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

117. A January 12, 2015 J.P. Morgan report summarized Scangos' positive statements:

Overall, the tone of CEO George Scangos' presentation – to a packed house – was positive as he reviewed the company's core commercial business (currently capturing ~38% of the MS market)....

118. On January 29, 2015, Defendants caused the Company to announce its 4Q 2014 results, reporting Tecfidera revenues of \$916 million, or approximately 35% of total revenues. Defendants reiterated that Tecfidera performance remained strong and stated that they had not seen any meaningful change in discontinuation rates:

[W]e believe that [Tecfidera] will continue to grow in the US and will grow substantially in international markets, so that we anticipate that 2015 will be another year of meaningful growth for Tecfidera and for our portfolio of MS products, in general.

* * *

Tecfidera continued to demonstrate its strong performance, which we believe is a testament to its attractive product profile, combining strong efficacy, favorable safety and tolerability, and the convenience of oral administration.

* * *

Importantly, we have not noticed a meaningful change in Tecfidera discontinuation rates. We are actively engaging physicians to ensure proper education on the label update. And we believe in the continued growth potential of the product in the US.

- and 16%" over 2014, with "Tecfidera [as] the largest contributor to our overall revenue growth." When asked what Defendants were seeing "in terms of physician reactions to the PML case that might be slowing intake," defendant Kingsley reiterated that there was no "meaningful change" because physicians were not pulling patients off Tecfidera, and that Defendants "have the right education [for physicians] in place."
- 120. In response to Defendants' false and misleading statements, Biogen's stock increased \$2.07 per share or 0.59% on January 29, 2015 and increased \$35.91 per share or 10.17% on January 30, 2015.

- and Company wrote on January 30, 2015 that "2015 Guidance Should Also Allay Fears, Especially Given B[iogen]'s Track Record Of Conservatism," after noting that Biogen acknowledged but downplayed a deceleration in prescription trends. Deutsche Bank also wrote on January 30, 2015 that "FY14 results were driven by the strength of Tecfidera with 4Q revenues.... Management continues to see Tecfidera growing in 2015. Guidance was in line; however given B[iogen]'s history with beating expectations, we expect the guidance sets them up well to perform in 2015."
- 122. That same day, Defendants held a conference call to discuss its 4Q 2014 results which defendants Scangos, Clancy, and Kingsley attended. On the January 29, 2015 earnings call, defendant Scangos made the following false and misleading statements regarding Tecfidera's growth:

[W]e believe that [Tecfidera] will continue to grow in the US and will grow substantially in international markets, so that we anticipate that 2015 will be another year of meaningful growth for [Tecfidera] and for our portfolio of MS products, in general.

the US and will grow substantially in international markets" such that he expected "2015 will be another year of meaningful growth for Tecfidera" were false and misleading because Tecfidera sales had declined in almost every region by the end of 2014 and into 2015, leading the Company to lower Tecfidera sales goals by January 2015. These statements were also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer

prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug. In addition, these statements were false and misleading for the additional reason that, at a minimum for the second quarter of 2015, Defendants had caused Biogen to lower sales goals across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

124. On the same call, defendant Kingsley made the following false and misleading statements regarding Tecfidera discontinuation rates following the PML incident:

Importantly, we have not noticed a meaningful change in [Tecfidera] discontinuation rates. We are actively engaging physicians to ensure proper education on the label update. And we believe in the continued growth potential of the product in the US.

125. Defendant Kingsley's statements that Defendants "have not noticed a meaningful change in Tecfidera discontinuation rates" and that they "believe in the continued growth potential of the product in the U.S." were false and misleading because defendant Kingsley knew that sales were down in almost every region in the United States. Defendant Kingsley also later admitted that Defendants knew the PML death had led to a significant change to the safety profile and physicians' confidence in Tecfidera. These statements were also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug. In addition, the statement that

Defendants believed in the continued growth potential of Tecfidera was false and misleading for the additional reason that, at a minimum for the second quarter of 2015, Defendants had caused Biogen to lower sales goals across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

126. On the same earnings call, defendant Clancy made the following false and misleading statements regarding Tecfidera performance:

We expect revenue growth between 14% and 16%.... Our plan assumes [Tecfidera] will represent the largest contributor to our overall revenue growth.

between 14% and 16%" with "Tecfidera ... represent[ing] the largest contributor to our overall revenue growth" was false and misleading because by late 2014, Tecfidera sales had steeply declined in almost every region in the United States. This statement was also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug. In addition, defendant Clancy's statement that revenue would grow between 14-16% was false and misleading for the additional reason that, at a minimum for the second quarter of 2015, Defendants had caused Biogen to lower sales goals for its leading drug by that same percentage – 15% – across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive

pressures.

128. On the same call, in direct response to analyst questions, defendants Clancy and Kingsley made the following false and misleading statements regarding Tecfidera performance and discontinuation rates:

Defendant Clancy

We think this is still a very meaningful growth with [Tecfidera] that's embedded in the guidance for this year.

* * *

Brian Abrahams - Wells Fargo Securities, LLC - Analyst

[I]nterestingly, you're not seeing any increase in discontinuations.... what are you seeing, in terms of physician reactions to the PML case that might be slowing uptake, and what sorts of educational initiatives do you think will be needed to help physicians work around this?

Defendant Kingsley

So we think we have the right education in place. We have to keep executing it, making sure that things continue to happen.

[T]he lack of any meaningful change that we see – or we believe we're seeing – in the discon[tinuation] rate is encouraging, because it doesn't suggest there's such a change in the profile that people are anxious to pull patients out, but on the contrary.

129. Defendant Kingsley's statements that the Company was "executing" on its educational initiatives with physicians in light of the PML death, and there was no change in the profile of Tecfidera that was causing physicians to pull patients off the drug were false and misleading because Defendants knew sales were down in almost every region in the United States. Defendant Kingsley also later admitted that Defendants knew the PML death had led to a significant change to the safety profile and physicians' view of Tecfidera. These statements were also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical

institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug. In addition, these statements were false and misleading for the additional reason that, at a minimum for the second quarter of 2015, Defendants had caused Biogen to lower sales goals across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

- 130. Defendant Clancy's statement that there was "still a very meaningful growth with Tecfidera that's embedded in the guidance for this year" was false and misleading because he failed to disclose that by late 2014 and into 2015 sales were down in almost every region in the United States. These statements were also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug, and Defendants lowered sales goals for, at a minimum, the second quarter of 2015 across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.
- 131. Biogen's stock jumped \$35.91 per share on January 30, 2015, an increase of more than 10%.
- 132. During a February 25, 2015 conference, defendant Kingsley stated that "Tecfidera is a terrific product that is going to perform very well in the market. It is –

from the time it launched, it has really driven a lot of conversion in the market or acceleration in the conversion of the market to orals. It's got a good profile.... We've talked in the past we are getting about a third of new starts, which is a very good thing and we're getting a nice portion of the switch pool as well."

133. Defendant Kingsley also downplayed the impact of the PML incident, stating that there was no hesitancy by physicians to prescribe Tecfidera, calling the drug "resilient" and reaffirming Tecfidera as a "meaningful growth driver":

You would expect to see some hesitancy among some set of physicians before you get them to have a conversation about that, but the product has been quite resilient...in light of that. In 2015, we think it is still a meaningful growth driver. US will still see growth and we have geographic expansion as we are rolling out to more markets outside the US.

- 134. When asked "do you think a lot of the PML noise or news has gotten out there and have you started to see a reacceleration of things when you go out into the what's the feedback from the salesforce?" defendant Kingsley responded that Tecfidera was still "capturing a third of new starts that makes a pretty strong statement about what the market's perception of the product is, including safety," emphasizing that there was "no evidence" of "any change in the discontinuation rate."
- 135. Defendant Kingsley's statements that: (1) Tecfidera was "going to perform very well in the market"; (2) "capturing a third of new starts that makes a pretty strong statement about what the market's perception of the product is, including safety"; (3) the Company was not seeing hesitancy among physicians in light of Tecfidera being "resilient" and that "it is still a meaningful growth driver; and (4) there was "nothing to signal" that Tecfidera's discontinuation rate was "not consistent with historical averages" were false and misleading because by late 2014 and into 2015, sales had declined in most

regions. Defendant Kingsley also later admitted that Defendants knew the PML death had led to a significant change to the safety profile and physicians' view of Tecfidera. These statements were also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug. In addition, these statements were false and misleading for the additional reason that, at a minimum for the second quarter of 2015, Defendants had caused Biogen to lower sales goals across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

- announce its 1Q 2015 results. Tecfidera revenues were \$825 million, below the market's consensus estimates. For the first time, Defendants partially acknowledged that the PML death was impacting Tecfidera sales in the United States and Germany. Defendant Scangos noted that "Tecfidera had a more challenging quarter, due to a number of issues, including an overall slowing of the MS market, the recent launch of Plegridy, the single PML case reported last year, and some first-quarter financial dynamics...." In response to this partial disclosure of the PML incident's impact on Tecfidera revenue, Biogen's stock dropped \$28.57 per share, or 6.64%, on April 24, 2015.
- 137. Yet Defendants continued to mislead shareholders regarding the true extent of the negative impact from the PML death on Tecfidera performance. Defendant

Scangos reaffirmed that "our long-term outlook for Tecfidera, and for our entire MS portfolio, remains strong." Defendant Clancy notably did not update or correct the Company's January guidance of 14-16% revenue growth.

138. According to defendant Kingsley, the Company had successfully educated physicians about the PML death and that prescribing patterns were returning to normal. While physicians saw "some hesitance" among patients, Kingsley stated that "our internal market research suggests that physician intent to prescribe may be improving. We believe these data indicate that we are assisting physicians in putting the updated label into context."

In an effort to blunt the partial corrective information, defendant Kingsley's statement that "physician intent to prescribe may be improving" was false and misleading because Tecfidera sales continued to be significantly lower following the PML death. In addition, defendant Kingsley's statement that "our internal market research suggests that physician intent to prescribe may be improving" was false and misleading because Defendants later admitted that to the contrary, Biogen's market research indicated a moderation in physician intent to prescribe. Defendant Kingsley's statement that "physician intent to prescribe may be improving" was also false and misleading because, consistent with what ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug, and Biogen had lowered sales goals across "all territories and regions" for at least the second quarter of

2015 as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

- 140. Defendant Clancy's statement that "we won't be updating our formal guidance this quarter.... we continue to expect [Tecfidera] will represent the largest contributor to our overall revenue growth" was false and misleading because the 14-16% metric was no longer achievable based on Tecfidera sales trends as of March 2015. This statement was also false and misleading because Defendants had caused Biogen to lower sales goals for the second quarter of 2015 by 15% across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.
- 141. Defendant Scangos' statement that "our long-term outlook for Tecfidera ... remains strong" was false and misleading because Tecfidera's trajectory had changed immediately following the announcement of the PML death, and sales continued to be down across the United States, forcing the Company to lower compensation thresholds. This statement was also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug, and Defendants had caused Biogen to lower sales goals for the second quarter of 2015 across "all territories and regions" as a result of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

- 142. Analysts acknowledged the apparent impact of the PML death on Tecfidera, but accepted Defendants' outlook. A Deutsche Bank report on April 24, 2015 titled, "Defending [Biogen]. Weakness on 1Q miss is overdone," noted that the stock's "weakness is overdone in the light of MGMT comments. The Management noted that if the US trajectory on Tecfidera does not improve, they may come in at the lower end of the previously provided revenue guidance...."
- 143. Additionally, Defendants' disclosures confirmed that the Company's 2014 10-K and April 24, 2015 Form 10-Q, which included certifications signed by defendants Scangos and Clancy, required under the Sarbanes-Oxley Act of 2002 ("SOX Certifications") were likewise false and misleading when made. In particular, these SOX Certifications certified that the financial "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."
- 144. The 2014 10-K additionally included management's assessment of internal control over financial reporting, which was likewise false and misleading when made. Specifically, the 2014 10-K stated, in pertinent part:

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 1992 Internal Control — Integrated Framework.

Based on our assessment, our management has concluded that, as of December 31, 2014, our internal control over financial reporting is effective based on those criteria.

145. At a May 6, 2015 Deutsche Bank conference, when questioned again

about the PML incident's impact on Tecfidera, defendant Clancy stated that any impact had stabilized:

I mean, certainly as you noted that there was a safety event that we talked about in October on Tecfidera that seems to have had a little unfavorable impact on the safety perceptions that we saw register in a number of our kind of the way we kind of do attitudinal surveys with physicians, that has stabilized.

* * *

But we fundamentally believe that we got, we still have upward trajectory on [Tecfidera] from a share perspective, from a patient perspective, no doubt about it.

146. Defendant Clancy's statement that "we fundamentally believe that we got, we still have upward trajectory on Tecfidera" was false and misleading because he knew that the current trajectory of Tecfidera in the United States had changed immediately after the PML death, and that it still had not recovered at the time of the misleading statement. The statement was also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug, and Defendants had caused Biogen to lower sales goals for the second quarter of 2015 across "all territories and regions" because of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

147. At a May 13, 2015 Bank of America healthcare conference, Doug Williams ("Williams"), Biogen's EVP of Research & Development, emphasized that

physician perceptions of Tecfidera's safety profile were the same as prior to the PML death:

We've done some survey work recently that would suggest that physicians have kind of digested the information, taken it on board and their perspective about the safety profile of the drug has kind of gotten back to where it was before the PML event. That's sort of the first step in being able to get back on that trajectory of putting new patients on the drug.

148. Williams' statement that physicians had "digested the information, taken it on board and their perspective about the safety profile of the drug has kind of gotten back to where it was before the PML event" was false and misleading because Defendants failed to disclose that sales of Tecfidera across the United States had not recovered to the level prior to the PML death. Defendant Kingsley also later admitted that Defendants knew the PML death had led to a significant change to the safety profile and physicians' view of Tecfidera. Williams' statement was also false and misleading because, consistent with what it has been alleged that ABMs from around the country confirm was the case in other regions, Defendants were aware at a minimum that two very large medical institutions, the Shepherd Center in Atlanta and the University of Pennsylvania, were no longer prescribing Tecfidera and were discontinuing patients off the drug because physicians had lost confidence in the safety profile of the drug, and Defendants had caused Biogen to lower sales goals for the second quarter of 2015 across "all territories and regions" because of the "residual impact of the safety event" announced in October 2014 as well as competitive pressures.

149. Similarly, at a May 27, 2015 Sanford Bernstein conference, defendant Clancy reiterated that physicians' views of Tecfidera safety had "stabilized":

Certainly there was a safety event late last year where physician perceptions on the safety profile declined a little bit, still in a very good

competitive profile vis-a-vis other therapies in the marketplace. Those have stabilized, right.

- 150. Defendant Clancy further emphasized that Defendants "continue to see our share of capturing of new scripts and switched scripts higher than our share. That's usually an indication that we'll get upward momentum in the business" and that "we'd be surprised if we don't see forward momentum from here."
- 151. Defendant Clancy's statements that physician perceptions of Tecfidera's safety profile had "stabilized" and that "we'll get upward momentum in the business," such that "we'd be surprised if we don't see forward momentum from here" were false and misleading, because he failed to disclose that Tecfidera sales had significantly declined since late 2014. Defendants also later admitted that physician views of Tecfidera had not yet recovered.
- 152. Biogen's stock closed at \$402.92 per share on May 27, 2015, up \$10.04 per share from the previous day, an increase of more than 2%.

F. The Truth Emerges

- 153. On July 24, 2015, before the market opened, Defendants cut their previously confirmed guidance for revenue growth in half, attributing the change to Tecfidera performance and stating in a Form 8-K that "Biogen's mid-year update to its full year 2015 financial guidance consists of the following components: Revenue growth is expected to be approximately 6% to 8% compared to 2014, a decrease from prior guidance based largely on revised expectations for the growth of Tecfidera."
- 154. On the July 24, 2015 earnings call that same day, Defendants disclosed the actual impact of the PML death and Tecfidera's changed safety profile on Tecfidera:

Defendant Scangos

We had expected to see a reacceleration of Tecfidera this quarter, but that did not happen to any appreciable extent.

* * *

Defendant Kingsley

We believe the safety event reported in late 2014 has created greater caution on the part of both physicians and patients about switching to orals. Our US market research indicates a moderation in physician intent to prescribe, though in Q2, Tecfidera continued to gain patients in the US.

* * *

Defendant Clancy

Let me turn to our updated full year 2015 guidance. We now expect revenue growth between 6% and 8%. This substantial decrease from our prior guidance is primarily driven by a change in our estimate for Tecfidera's trajectory. Our balance of year forecast assumes limited patient growth for Tecfidera in the United States.

- 155. Appearing on CNBC prior to markets opening on July 24, 2015, Jim Cramer stated that Biogen's announcement was "a horrendous guide down" from the previous "guidance for their MS drug Tecfidera" and that Biogen's disclosure was "shattering" and a "gaffe[] to the people who have loved this stock."
- 156. Analysts on the earnings call questioned management's abrupt about-face on Tecfidera. Defendant Kingsley admitted in response to an analyst's question that the October 22, 2014 announcement was a "significant change statement for the profile of Tecfidera, given its very pristine safety profile at the time." Speaking on behalf of the Company (*i.e.*, at the behest of Defendants), Williams conceded that Biogen saw "a modest but not trivial increase in discontinuations in Tec[fidera] in the United States."
- 157. In response to the July 24, 2015 disclosures, Biogen's stock price plummeted over 20% in a single day.
 - 158. On July 27, 2015, J.P. Morgan stated that "management credibility is

clearly tarnished, and there's little doubt that the company is now stuck in the penalty box.... The messy 1Q report was supposed to be a one-time anomaly. Instead, 2Q results and revised guidance seem to indicate the problem is much more systemic. It's no wonder that investor confidence is shaken." Morgan Stanley echoed J.P. Morgan, stating the same day that "[Biogen management] has a credibility issue with its seeming inability to stem the now sig[nificant] decline in base business performance."

- 159. At a September 18, 2015 Bank of America Merrill Lynch health care conference, defendant Kingsley acknowledged that the PML death had a significant impact on the safety profile of the drug: "[i]t was clear to us that we were going to get a some kind of a downtick in the safety profile that would have some kind of an impact on physician behavior, but we couldn't tell." Kingsley also admitted that the FDA label change was a meaningful change statement: "the [Tecfidera] label was so clean [prior to the PML incident], the first PML event was a pretty big change statement for a broad base of physicians who were very comfortable with having essentially no safety issues."
- 160. As EVP for Commercial Operations, defendant Kingsley was responsible for overseeing Biogen's sales force and commercial operations. On October 9, 2015 Defendants announced that Kingsley "will leave the company and a search has been initiated for a permanent replacement." When the Defendants caused the Company to announce his departure, defendant Scangos stated that Kingsley had been responsible for the launch and introduction of Tecfidera into the market. Defendant Kingsley's abrupt departure occurred only two months after the Company's disclosures regarding Tecfidera. RBC Capital Markets reported that "Biogen was down almost 4% today ... due to uncertainty of the announced resignation of Tony Kingsley, EVP of Global

Commercial Operations. Our conversations with investors indicate concerns behind his departure at the end of the quarter. Investors view that the business might not be improving...."

- 161. On October 21, 2015, Defendants announced that Biogen would eliminate approximately 11% of its workforce.
- 162. Additionally, the price of the Company's stock has only continued its freefall and presently trades for around \$291 per share.
- 163. Accordingly, as a result of Defendants' actions, the Company has suffered damages. These damages include (but are not limited to) decimation of the Company's share price, and loss of reputation and standing.
 - G. The Individual Defendants Cause the Company to Issue False and Misleading Statements in the 2015 Proxy in Violation of Section 14(a) of the Exchange Act
- 164. On April 30, 2015, the Individual Defendants caused Biogen to disseminate to Biogen shareholders the Company's 2015 Proxy Statement in connection with the Company's annual shareholder meeting (the "2015 Proxy"). The Individual Defendants drafted, approved, reviewed and/or signed the 2015 Proxy before it was filed with the SEC and disseminated to Biogen shareholders. The Individual Defendants knew, or were deliberately reckless in not knowing, that the 2015 Proxy was materially false and misleading.
- 165. For one, in the 2015 Proxy, the Board claimed that "our executive compensation program embodies a pay-for-performance philosophy that supports our business strategy and aligns the interests of our executives with our stockholders. In particular, our compensation program rewards financial, strategic and operational

performance and the goals set for each performance category support our long-range plans."

- based, in part, on the Company's financial and operational goals, as well as long-range plans. Necessarily this means that if increasing and maximizing expected revenue are used to justify increased executive compensation (as they were in the 2015 Proxy) then a significant decrease in operational performance and revenues should have a negative effect on executive compensation. In this regard, the 2015 Proxy failed to provide any indication that the PML death, or the underlying cause of the PML death, had materially impacted Tecfidera sales and caused physicians to stop prescribing Tecfidera or switch patients onto other therapies out of safety concerns. This, in turn, was having and would continue to have a significant, detrimental impact on the Company's revenue and base business performance. This is particularly true in light of Tecfidera's admitted importance as a core product of the Company.
- 167. Further, the 2015 Proxy utterly failed to disclose that the following regarding the Company's core product Tecfidera was untrue: (a) the overall risk and safety profile of Tecfidera was unchanged; (b) doctors were continuing to prescribe it in increased numbers, and the number of patients as "new starts" on the drug continued to indicate sustained growth momentum; (c) doctors were not discontinuing patients off Tecfidera; and (d) Tecfidera would continue to drive strong revenue growth. As these issues directly involved the Company's core operations, this renders the 2015 Proxy materially false and misleading.

DERIVATIVE AND DEMAND ALLEGATIONS

- 168. In light of the foregoing, on August 28, 2015, Plaintiff issued a demand letter pursuant to Delaware law (the "Demand") on the Board to investigate and commence an action against certain current and/or former directors and executive officers of the Company. A true and correct copy of the Demand is attached hereto as Exhibit A.
- 169. Thereafter, Plaintiff's counsel received a letter dated September 18, 2015 from James R. Carroll ("Carroll") of the law firm Skadden, Arps, Slate, Meagher & Flom LLP ("Skadden"), which purportedly represented the Company. Mr. Carroll's letter asked that we "promptly provide all available information regarding Mullaney's purchase and sales of Biogen securities." A true and correct copy of Mr. Carroll's letter is attached hereto as Exhibit B.
- 170. Shortly thereafter, Plaintiff's counsel received a letter dated October 29, 2015 from Jordan D. Hershman ("Hershman") of the law firm Morgan, Lewis & Bockius LLP ("Morgan Lewis"), which purportedly represented a "special investigative committee" of the Board known as the "Demand Committee," which was comprised of defendants Schenk and Mulligan. Mr. Hershman's letter also requested that Plaintiff provide "appropriate proof" that she has been "a shareholder of the Company continuously since at least January 29, 2015." A true and correct copy of Mr. Hershman's letter is attached hereto as Exhibit C.
- 171. Even though neither Mr. Carroll's nor Mr. Hershman's letter provided any legal authority to condition a response and/or investigation of the Demand on the receipt of proof of Plaintiff's stock holdings, on October 31, 2015, Plaintiff's counsel provided Mr. Hershman with redacted proof of Plaintiff's ownership of Biogen stock. In that communication, Plaintiff's counsel indicated that it was assumed that Mr. Hershman's

letter trumped Mr. Carroll's letter, and asked to be advised if that assumption was in error. Moreover, the letter requested clarification as to whether the Demand Committee was a "Special Litigation Committee," as defined by Delaware Law.

- 172. Thereafter, Plaintiff's counsel received a letter dated March 16, 2016 from Mr. Hershman of Morgan Lewis, which formally refused the Demand (the "Refusal"). The Refusal stated that the Demand Committee (which was now being referred to as the "Special Committee")⁸ had "unanimously determined that the allegations and demands of the Demand letter provide no basis upon which to bring a valid claim against any director or officer of the Company." Accordingly, Plaintiff was informed that the Demand was rejected. A true and correct copy of the Refusal is attached hereto as Exhibit D.
- 173. The Refusal consisted of a series of generalized conclusions as to why the allegations in the Demand purportedly lacked merit. Among other things, the Refusal stated that the Special Committee's purported "investigation" involved "extensive document collection, review and analysis," that Morgan Lewis collected over 450,000 emails and attachments and "reviewed and analyzed thousands of hard copy documents." Further, the Refusal stated that Morgan Lewis "interviewed thirteen current and former employees with knowledge pertinent to the investigation," including "the Company's CEO, CFO, and members of its finance, commercial, reporting, investor relations, medical, and accounting departments."
- 174. Given that the conclusory Refusal created more questions than it answered, on May 3, 2016, Plaintiff's counsel sent another letter to Mr. Hershman. A true and correct copy of the May 3, 2016 letter is attached hereto as Exhibit E.

⁸ As such, the terms Special Committee and Demand Committee are used interchangeably herein.

- 175. First, the May 3, 2016 letter once again posed the still unanswered question from Plaintiff's October 31, 2015 letter regarding whether the Demand Committee was a Special Litigation Committee, as defined by Delaware law. Plaintiff's counsel had not then and has not ever received an answer to this simple, foundational question.
- 176. Next, the May 3, 2016 letter requested a copy of all documents reviewed in connection with the Demand, and a list of any and all witnesses interviewed as part of the investigation. Further, the May 3, 2016 letter requested a copy of any report prepared by the Special Committee that helped form the basis of the Special Committee's recommendation to reject the Demand. Finally, the May 3, 2016 letter requested copies of any and all documents regarding or reflecting the Board's appointment of the Special Committee to investigate the Demand and any authorization of the Special Committee to evaluate the Demand and to make a recommendation to the Board in connection with refusing the Demand. *See* Exhibit E.
- 177. It has now been eight months since Plaintiff's counsel sent the May 3, 2016 letter, and Plaintiff has received no response to the letter. Nor has Plaintiff received any of the additional information or clarification on the points referenced in that letter. In fact, Plaintiff still has not even been informed of whether the Special Committee created and/or relied on a formal report in issuing the Refusal.
- 178. Accordingly, the Refusal is wholly improper and fatally deficient. By issuing the conclusory Refusal, Defendants have attempted to insulate their investigation from any scrutiny, which is patently unreasonable. The Special Committee (through the Refusal) has merely recited the conclusion that refusing the Demand was proper, without

adequately explaining how the Special Committee reached that conclusion. Defendants and the Special Committee have essentially asked Plaintiff to "take their word for it" regarding the thoroughness of the investigation.

- 179. Thus, given the Board's deliberate and repeated efforts to hide any and all substantive details of the purported Special Committee's investigation, Plaintiff and the Court have been insulated from substantive reasons regarding why the Refusal was issued and why the Board has declined to pursue these valuable claims. Plaintiff has not received a copy of any report (if one does exist), has not been made aware of the specifics of the documents relied upon by the Special Committee, nor has Plaintiff received any information regarding the formation and appointment of the Special Committee.
- 180. This secrecy is especially troubling because it is the wrongfulness of certain conduct—as opposed to the factual issue of whether certain conduct took place—that the Special Committee was tasked with investigating. The Board's and Special Committee's refusal to provide sufficient insight and detail into how the conclusions were reached most notably by failing to either create and/or provide a formal report raises additional unanswered questions. The failure to provide or even reference a formal report casts serious doubt on the adequacy of the "investigation." In the alternative, if such a report was created, Defendants have refused to provide such a report to Plaintiff, which is wholly improper.
- 181. Further, there is the issue of witness interviews. It is readily apparent that the Special Committee did not interview a single individual who would corroborate Plaintiff's claims of wrongful conduct, or a single potentially adverse witness. This was wholly improper, and provides ample reason to second guess the Board's and Special

Committee's decision, and the Refusal itself. At a minimum, a reasonable investigation would include an interview with Dr. Thrower, or some other individual associated with the MS Institute at Shepherd Center with comparable knowledge of the safety profile of Tecfidera.

Finally, and perhaps most troubling, it does not appear that the Board 182. and/or Special Committee ever hired any independent counsel to assist in the investigation of the Demand. Notwithstanding that the Special Committee engaged Morgan Lewis to assist it in its investigation, it is clear that Morgan Lewis is not independent counsel. For example, despite engaging Morgan Lewis in October 2015 to investigate the matters raised in the Demand, in April 2016, Morgan Lewis hosted a "CEO Forum" on "Drug Discovery & Development," which featured Biogen's CEO, defendant Scangos. In the press release announcing the CEO Forum, Morgan Lewis touted defendant Scangos as being "named one of the world's ten best performing CEOs."9 Accordingly, although defendant Scangos is perhaps the chief culprit responsible for the Company's problems, which the Special Committee and its counsel (i.e., Morgan Lewis) should have independently investigated with the most vigor, Morgan Lewis instead decided to promote and feature him in their CEO Forum. This was wholly improper and only further serves to underscore the non-independent and inadequate investigation performed regarding the serious issues raised in the Demand. 10

⁹ See https://www.morganlewis.com/news/morgan-lewis-ceo-forum-to-feature-biogens-george-scangos-drug-development-and-discovery-discussion (last visited Jan. 12, 2017).

¹⁰ It is additionally worth noting that attorneys from Morgan Lewis have admittedly represented Biogen in the past. For instance, according to attorney profiles on Morgan Lewis' website, attorneys from Morgan Lewis have represented Biogen in, at least, "its strategic alliance with Aveo Pharmaceuticals" and "in its equity investment in CalciMedica." *See* https://www.morganlewis.com/bios/williamperkins (last visited Jan. 12, 2017).

183. The Board's prejudgment and conclusory "analysis" of the merits of the claims set forth in the Demand, which was not aided by any independent counsel, is improper and demonstrates the Board's lack of diligence and good faith. In short, the entire "process" was procedurally deficient. The Board's abdication of its duty to properly investigate the Demand and to produce a formal report (or in the alternative, to provide Plaintiff with any formal report that was created or to even acknowledge that a formal report was created) was not reasonable, and was a decision made in bad faith, and is not entitled to the protections of the business judgment rule. Thus, Plaintiff has been left with no other recourse than filing this Action, and given the wrongful, bad-faith refusal of the Demand, this Action must be allowed to proceed.

COUNT I AGAINST ALL INDIVIDUAL DEFENDANTS FOR BREACH OF FIDUCIARY DUTIES

- 184. Plaintiff incorporates by reference all preceding and subsequent paragraphs of this Complaint as if fully set forth herein.
- 185. As alleged herein, each of the Individual Defendants had a fiduciary duty to, among other things, ensure that the Company was operated in a lawful manner, and to exercise good faith to ensure that the Company's financial statements were prepared in accordance with GAAP, and, when put on notice of problems being experienced with the Company's business practices and operations, should have exercised good faith in taking appropriate action to correct the misconduct and to prevent its recurrence.
- 186. The Individual Defendants willfully ignored the obvious and pervasive problems being experienced with Biogen's internal controls practices and procedures, and failed to make a good faith effort to correct these problems or prevent their

recurrence, which ultimately led to, *inter alia*, the decimation of the Company's stock price and damage to its goodwill.

- 187. As alleged in detail herein, each of the Individual Defendants (and particularly the Audit Committee Defendants) had a duty to ensure that Biogen disseminated accurate, truthful and complete information to its shareholders.
- 188. The Individual Defendants violated their fiduciary duties of care, loyalty, and good faith by causing or allowing the Company to disseminate to Biogen shareholders materially misleading and inaccurate information through, *inter alia*, Biogen's SEC filings and other public statements and disclosures as detailed herein. These actions could not have been a good faith exercise of prudent business judgment.
- 189. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Biogen, for which they are legally responsible. In particular, the Individual Defendants abused their positions of authority by causing or allowing Biogen to misrepresent material facts regarding the Company's products, its true financial position, and its business prospects.
- 190. The Individual Defendants had a duty to Biogen and its shareholders to prudently supervise, manage and control the operations, business and internal financial accounting and disclosure controls of Biogen.
- 191. The Individual Defendants, by their actions and by engaging in the wrongdoing described herein, abandoned and abdicated their responsibilities and duties with regard to prudently managing the business of Biogen in a manner consistent with the duties imposed upon them by law. By committing the misconduct alleged herein, the Individual Defendants breached their duties of due care, diligence and candor in the

management and administration of Biogen's affairs, and in the use and preservation of Biogen's assets.

- 192. During the course of the discharge of their duties, the Individual Defendants knew or recklessly disregarded the unreasonable risks and losses associated with their misconduct, yet the Individual Defendants caused Biogen to engage in the illicit scheme complained of herein, which they knew had an unreasonable risk of damage to Biogen, thus breaching their duties to the Company. As a result, the Individual Defendants grossly mismanaged Biogen.
- 193. As a direct and proximate result of the Individual Defendants' foregoing breaches of fiduciary duties, the Company has suffered significant damages, as alleged herein.
- 194. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.
 - 195. Plaintiff, on behalf of Biogen, has no adequate remedy at law.

COUNT II AGAINST ALL INDIVIDUAL DEFENDANTS FOR UNJUST ENRICHMENT

- 196. Plaintiff incorporates by reference and realleges each and every allegation of the Complaint set forth above, as though fully set forth herein.
- 197. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of Biogen in the form of, *inter alia*, salaries, bonuses, stock options, and/or other forms of executive compensation.
- 198. Plaintiff, as a shareholder and representative of Biogen, seeks restitution from these Individual Defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by these Individual

Defendants, and each of them, from their wrongful conduct and fiduciary breaches.

COUNT III

AGAINST THE INDIVIDUAL DEFENDANTS FOR VIOLATIONS OF SECTION 14(A) OF THE SECURITIES EXCHANGE ACT OF 1934

- 199. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.
- 200. Rule 14a-9, promulgated pursuant to §14(a) of the Securities Exchange Act of 1934, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. §240.14a-9. Specifically, the 2015 Proxy violated §14(a) and Rule 14a-9 because it solicited Biogen shareholder votes for, *inter alia*, executive compensation and director nominations. In this regard, the 2015 Proxy was likewise false and misleading when issued because the 2015 Proxy failed to provide any indication that the PML death, or the underlying cause of the PML death, had materially impacted Tecfidera sales and caused physicians to stop prescribing Tecfidera or switch patients onto other therapies out of safety concerns. This, in turn, was having and would continue to have a significant, detrimental impact on the Company's revenue and base business performance.
- 201. Moreover, the 2015 Proxy utterly failed to disclose that it was untrue that:

 (a) the overall risk and safety profile of Tecfidera was unchanged; (b) doctors were continuing to prescribe it in increased numbers, that the number of patients as "new starts" on the drug continued to indicate sustained growth momentum; (c) doctors were not discontinuing patients off Tecfidera; and (d) Tecfidera would continue to drive strong

revenue growth.

202. In the exercise of reasonable care, the Individual Defendants should have known that the statements contained in the 2015 Proxy were materially false and misleading.

203. The misrepresentations and omissions in the 2015 Proxy were material. The misrepresentations and omissions in the 2015 Proxy were essential links in the accomplishment of the continuation of the Individual Defendants' scheme by which they claim to adhere to a "pay-for-performance" policy in making executive compensation decisions whereby the interests of management and stockholders are aligned.

204. In the exercise of reasonable care, the Individual Defendants should have known that the statements contained in the 2015 Proxy was materially false and misleading, and/or that the 2015 Proxy omitted material information. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the Proxy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

- A. Against all Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties;
- B. Directing Biogen to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws, and to protect the Company and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for

amendments to the Company's By-Laws or Articles of Incorporation, and taking such

other action as may be necessary to place before shareholders for a vote, a proposal to

strengthen the Board's supervision of operations and develop and implement procedures

for greater shareholder input into the policies and guidelines of the Board;

C. Awarding to Biogen restitution from the Individual Defendants, and each

of them, and ordering disgorgement of all profits, benefits and other compensation

obtained by the Individual Defendants;

Awarding to Plaintiff the costs and disbursements of the action, including D.

reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: January 13, 2017

RIGRODSKY & LONG, P.A.

By: /s/ Brian D. Long

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